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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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MARK S. ELLINGER, PH.D.
Fish & Richardson P.C., P.A.
Suite 3300
60 South Sixth Street
Minneapolis, MN 55402

EXAMINER	
ANGELL, JON E.	

ART UNIT	PAPER NUMBER
1635	10

DATE MAILED: 09/30/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/918,242	Applicant(s) EKKER ET AL.	
	Examiner J. Eric Angell	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-67* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-67* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4. ☐ Interview Summary (PTO-413) Paper No(s). _____
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Other: _____

DETAILED ACTION

Claims 1-67 are pending in the application.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-20 and 40-53, drawn to a morphant teleost embryo and a collection of morphants, classified in class 800, subclasses 8 and 9.

II. Claims 21-23 and 59-64 drawn to a method reducing the expression of a selected nucleic acid and for producing a teleost embryo, classified in class 800, subclass 21.

III. Claims 24-31, 39 and 65-67, drawn to a composition comprising a morpholino-modified polynucleotide, classified in class 536, subclass 24.5.

IV. Claims 32-36, drawn to a method for determining a phenotype associated with a selected nucleic acid, classified in class 800, subclass 3.

V. Claims 37 and 38, drawn to a method for determining if polypeptides are genetic interactors, classified in class 800, subclass 3.

VI. Claim 54, drawn to a method of identifying a nucleic acid associated with a disease condition, classified in class 800, subclass 3.

VII. Claim 55, drawn to a method for assessing the effect of a drug on a morphant, classified in class 800, subclass 3.

2. Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by another and materially different process. For example, the product (a teleost embryo with reduced expression of a nucleic acid) can be made by making mutations in the embryo genome such that expression of the targeted nucleic acid is reduced (i.e. knock-out embryos).

3. Inventions I and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation, different functions, or different effects. For example, Invention I is a teleost embryo, while invention III is a composition comprising a morpholino-modified polynucleotide. These Inventions are two distinct products because the embryo and the polynucleotide are structurally and chemically different compositions. Furthermore, the teleost embryo functions as an animal model system for testing various biological phenomena such as polypeptide interaction, nucleic acid- phenotype association, etc. while the function and effect of a morpholino modified nucleic acid is to bind to a target nucleic acid and alter the expression of the target nucleic acid.

4. Inventions II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process for using the product as claimed can be practiced with another materially different product. For instance the process of making a teleost embryo with reduced expression from a target nucleic acid can be practiced using a targeting vector that the integrates into the target gene of interest and reducing the expression of said target nucleic acid.

5. Invention I is related to Inventions IV-VIII as a product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process for using the product as claimed can be practiced with another materially different product. For example the methods encompass the use of an embryo with the reduced expression of a particular nucleic acid(s) wherein the reduction of expression is due to a modified polynucleotide. Alternatively, the methods could be performed using an embryo with the reduced expression of a particular nucleic acid(s) wherein the reduction of expression is due to the integration of a nucleic acid into the target nucleic acid,

6. Inventions IV-VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated because the inventions encompass different modes of operation, different functions, or different effects. For instance, the inventions have different method steps, thus the inventions have different modes of operation. Furthermore, the different inventions have different functions because the function of Invention IV is to determine a phenotype associated with a selected nucleic acid, while the function of Invention V is to determine if to polypeptides are genetic interactors, the function of Invention VI is to identify a nucleic acid associated with a disease condition, and the function of Invention VII is to assess the effect of a drug on a morphant.

7. Invention III is related to Inventions IV-VIII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in materially different processes. For example, the product (a morpholino modified polynucleotide) can be used to determine (1) a phenotype associated with a nucleic acid (Invention IV); or (2) if two polypeptides are genetic interactors (Invention V); or (3) to identify a nucleic acid associated

8. Invention II is unrelated to Inventions IV-VIII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects. For example, the function of Invention I is to produce a teleost embryo with reduced expression of a particular nucleic acid, while the function of Invention IV is to determine a phenotype associated with a selected nucleic acid, the function of Invention V is to determine if to polypeptides are genetic interactors, the function of Invention VI is to identify a nucleic acid associated with a disease condition, and the function of Invention VII is to assess the effect of a drug on a morphant.

9. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

10. Because these inventions are distinct for the reasons given above and the search required for each Group is different from searches required of the other Groups (because the different searches require different search strategies such as different search terms and searching different classifications), restriction for examination purposes as indicated is proper.

A teleost embryo defective in the development of the following tissue:

Species (i) pancreas
(ii) vasculature tissue
(iii) blood
(iv) eye
(v) central nervous system
(vi) muscle
(vii) backbone
(viii) head
(ix) limb
(x) pigment cell

Applicant is required under 35 U.S.C. 121 to elect a single (1) disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 40-51 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP §

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

12. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Eric Angell whose telephone number is (703) 605-1165. The examiner can normally be reached on M-F (8:00-4:30).

the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

J. Eric Angell
September 26, 2002

JEFFREY FREDMAN
PRIMARY EXAMINER